UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHARLES R. BLACKBURN and MICHELE ROSATI, Derivatively on Behalf of NOVAVAX, INC., Plaintiffs, v. STANLEY C. ERCK, GREGORY F. COVINO, JOHN J. TRIZZINO, GREGORY M. GLENN, JOHN A. HERRMANN III, GREGG H. ALTON, RICHARD H. DOUGLAS, MARGARET G. MCGLYNN, DAVID M. MOTT, RACHEL K. KING, MICHAEL A. MCMANUS, JR., JAMES F. YOUNG, and GARY C. EVANS, Defendants, and NOVAVAX, INC. Nominal Defendant	Case No. 1:22-cv-01417

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

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Plaintiffs Charles R. Blackburn and Michele Rosati (collectively, "Plaintiffs"), by and through their undersigned attorneys, bring this stockholder derivative complaint for the benefit of nominal defendant, Novavax Inc. ("Novavax" or the "Company"), against its Board of Directors (the "Board") and certain of its current and former executive officers to remedy defendants' violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended; breach of fiduciary duty for insider trading (*Brophy* claim) and failing to adequately oversee the Company's mission-critical compliance with manufacturing safety regulations (*Caremark* claim); and unjust enrichment. Plaintiffs' allegations are based upon their personal knowledge as to themselves and their own acts, and upon information and belief, developed from the investigation and analysis by Plaintiffs' counsel, including a review of publicly available information such as filings by Novavax with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record, as well as documents obtained pursuant to a Freedom of Information Act ("FOIA") request to the U.S. Food and Drug Administration ("FDA") and books and records produced in response to Plaintiffs' books and records demands pursuant to 8 Del. C. § 220 (the "220 Demands"). All such books and records are expressly incorporated into this Complaint. For the avoidance of doubt, this incorporation by reference does not change the pleading standard applicable to any motion to dismiss that may be filed in this case.

I. NATURE OF THE ACTION

1. Novavax is a late-stage biotechnology company that seeks to discover, develop and commercialize innovative vaccines to prevent serious infectious diseases and address urgent, global health needs. When the Covid-19 pandemic began in March 2020, Novavax had 127 employees engaged primarily in research, development and manufacturing activities. The

Company was at risk of being delisted from the Nasdaq stock exchange as its stock traded under $4 per share and had just enough cash to survive another six months.

2. Although the Company had never successfully brought a vaccine to market in its 35 year history, the Company announced its intention to develop a Covid-19 vaccine on February 26, 2020. On March 10, 2020, Novavax received $4 million in funding from the Coalition for Epidemic Preparedness Innovations, a global partnership among organizations to accelerate the development of vaccines for emerging infectious diseases.

3. Following this initial round of funding, Defendants lobbied for additional grants from government and private organizations. In mid-April 2020, and again in June 2020, when it believed additional funding was imminent, the Board granted over $70 million in equity compensation to the Company's senior executives "in recognition of the extraordinary work of Novavax employees to implement a new vaccine program against SARS-CoV-2 and to incentivize the additional work necessary to make the program successful."

4. In July 2020, Novavax announced that it was selected to participate in Operation Warp Speed ("OWS") and would likely receive over $1 billion in additional funds to support development of its Covid-19 vaccine. Thereafter, Defendants told shareholders that the Company was ramping up development and production of its vaccine candidate.

5. Having sold its own manufacturing facilities in 2019 to alleviate its cash crunch, beginning on July 23, 2020, Novavax announced that it had entered into agreements with contract development manufacturing organizations ("CDMOs") through which third-parties would manufacture the Company's vaccine.

6. Unknown to the public, beginning in approximately March 2021, the U.S. Food and Drug Administration ("FDA") identified a wide array of problems at the manufacturing facilities used by Novavax.

7. Defendants, however, continued to issue positive disclosures about the Company's efforts to develop its vaccine and obtain FDA approval. These disclosures caused Novavax stock to leap from approximately $19 per share in April 2020 to over $200 per share for most of 2021.

8. While Defendants were issuing this string of positive disclosures, and while the FDA's communications about manufacturing problems were being concealed, the Board sought and obtained shareholder ratification of the April and June 2020 equity awards on the basis that the windfall was "appropriate not only due to the achievement of critical milestones under exceedingly difficult conditions, but also because it serves to continue to encourage their extraordinary efforts towards the achievement of our key priorities and anticipated milestones in 2021."

9. The truth was revealed on October 19, 2021, when a *Politico* article revealed that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards," such that the timeline for approval was still a year away. *Politico* reported that the Company's production problems include "test[ing] the purity of the vaccine [with methods that] have fallen short of regulators' standards" and "prov[ing] that it can produce a shot that is consistently up to snuff."[1] For example, though it is "generally understood that each vaccine batch should reach at least 90 percent [purity]," Novavax "has struggled to attain anywhere close to that" and has shown "purity levels hovering around 70 percent." The article reported that U.S. officials lacked confidence in Novavax because its "manufacturing problems are seen as ***far more difficult***"

[1] *Id.*

than the "sanitary and design concerns" affecting another COVID-19 manufacturer, Emergent BioSolutions, Inc. In fact, when Novavax was awarded the OWS contract, U.S. officials had "repeatedly warned the [C]ompany that it risked running into problems in scaling up the manufacturing of the shot," and specifically "that Novavax would have difficulty ensuring that the vaccine consistently met the FDA's rigorous quality standards once the vaccine went into mass production – the exact problem that has now stymied the company for months."

10. Deepening the crisis at Novavax, while their positive disclosures were causing the Company's stock price to increase ten-fold, Defendants sold enormous amounts of stock at artificially inflated prices. Between the FDA's initial communications regarding manufacturing problems in March 2021 and October 2021, insiders sold nearly $90 million in Novavax stock at prices far in excess of the Company's stock price today. From a high of $248 per share in late September 2021, Novavax stock plummeted to a current price of under $50 per share, erasing billions of dollars in market capitalization.

11. These revelations precipitated the filing of a securities class action in this District against Novavax and certain of the defendants named herein, captioned *Sinnathurai v. Novavax, Inc., et al.*, Case No. 8:21-cv-02910 (the "Securities Fraud Class Action").

12. Plaintiffs served their 220 Demands upon the Company on December 30, 2021 (plaintiff Rosati) and January 28, 2022 (plaintiff Blackburn), both seeking to inspect Board documents related to director and management knowledge and/or oversight of the Company's compliance with manufacturing protocols and knowledge of material non-public information ("MNPI") concerning the same, including their relation to regulatory approval of Novavax's COVID-19 vaccine candidate. Following negotiations and entry into a confidentiality agreement, the Company produced over 2,300 pages of internal documents.

13. Also on May 20, 2022, Plaintiff's counsel submitted a FOIA request to the FDA requesting correspondence, inspection reports, complaints, and/or regulatory action taken by the FDA as to Novavax or FUJIFILM Disoynth Biotechnologies regarding manufacturing deficiencies at its College Station, Texas and/or Morrisville, North Carolina facilities. The FDA thereafter produced approximately 130 pages of responsive materials.

14. Due to the information produced in response to the 220 Demands and the FOIA request, Plaintiffs did not make a litigation demand prior to filing suit because making a demand would be a futile and useless act.

15. At least half of the Company's current Board could not give disinterested and independent consideration to a litigation demand because four of the eight current directors engaged in insider trading on the basis of MNPI in breach of their duty of loyalty and were thus unjustly enriched; because at least four of the eight current directors knew or if exercised their duty of loyalty would have known of the grossly deficient manufacturing controls and procedures, yet allowed misleading statements to be disseminated; because the entire Board failed to oversee manufacturing controls and compliance with current good manufacturing practices ("cGMPs"); and because the entire Board sought and obtained shareholder ratification of the April 2020 equity awards on the basis that they were justified due to Defendants' efforts to develop the vaccine, while concealing the extensive manufacturing problems that undermined their entitlement to the awards. As a result, a majority of the Board is unable to impartially consider whether to bring the claims asserted in this action.

II. JURISDICTION AND VENUE

16. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this Complaint involves a federal question, namely violations of Section 14(a) of the Exchange Act. Pursuant to 28 U.S.C. § 1367(a), the Court has supplemental jurisdiction over the state law

claims asserted herein. This is not a collusive action to confer jurisdiction upon a court of the United States which it would not otherwise have.

17. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

III. PARTIES

Plaintiffs

18. Plaintiff Charles R. Blackburn purchased shares of Novavax stock in October 2017 and has continuously owned his Novavax stock since that date.

19. Plaintiff Michele Rosati purchased shares of Novavax stock in 2020 and has continuously owned her Novavax stock since that date.

Nominal Defendant

20. Nominal Defendant Novavax is a Delaware corporation with its principal executive offices in Gaithersburg, Maryland. The Company's common stock trades on the Nasdaq under the symbol "NVAX."

Defendants

21. Defendant Stanley C. Erck ("Erck") has served as Chief Executive Officer ("CEO"), President, and a director of the Company since 2009. He is named as a defendant in the Securities Fraud Class Action. Erck received $2,771,685 in total compensation from the Company for the fiscal year ended December 31, 2017; $4,158,398 in total compensation from the Company for the fiscal year ended December 31, 2018; $2,438,562 in total compensation from the Company for the fiscal year ended December 31, 2019; and $48,086,018 in total compensation from the

Company for the fiscal year ended December 31, 2020. Between 2017 and 2020, Erck's publicly reported income from sources other than the Company was approximately $350,000.

22. Defendant Gregory F. Covino ("Covino") served as Chief Financial Officer ("CFO"), Treasurer, and an Executive Vice President ("EVP") of the Company from November 16, 2020 to April 12, 2021. He is named as a defendant in the Securities Fraud Class Action.

23. Defendant John J. Trizzino ("Trizzino") has served as the Company's Chief Business Officer since March 2018, Chief Commercial Officer since November 2020, and an EVP of the Company since June 2020. He served as Interim CFO from April 12, 2021 to August 16, 2021. He is named as a defendant in the Securities Fraud Class Action.

24. Defendant Gregory M. Glenn ("Glenn") has served as the Company's President, Research and Development since March 2016. He is named as a defendant in the Securities Fraud Class Action.

25. John A. Herrmann III ("Herrmann") has served as EVP and Chief Legal Officer since June 2020 and Corporate Secretary since April 2010. He served as Senior Vice President from June 2014 until June 2020, as General Counsel from March 2012 until June 2020, and as Executive Director, Legal Affairs from April 2010 until March 2012.

26. Defendant Gregg H. Alton ("Alton") has served as a director of Novavax since November 2020.

27. Defendant Richard H. Douglas ("Douglas") has served as a director of Novavax since 2010. He is a member of the Board's Research and Development Committee (the "R&D Committee").

28. Defendant Margaret G. McGlynn ("McGlynn") has served as a director of Novavax since December 2020.

29. Defendant David M. Mott ("Mott") has served as a director of Novavax since June 2020. He is a member of the R&D Committee. Mott received $727,332 in total compensation from the Company for the fiscal year ended December 31, 2020.

30. Defendant Rachel K. King ("King") has served as a director of Novavax since 2018.

31. Defendant Michael A. McManus, Jr. ("McManus") has served as a director of Novavax since 1998. McManus received $246,512 in total compensation from the Company for the fiscal year ended December 31, 2017; $241,678 in total compensation from the Company for the fiscal year ended December 31, 2018; $134,296 in total compensation from the Company for the fiscal year ended December 31, 2019; and $876,252 in total compensation from the Company for the fiscal year ended December 31, 2020. McManus's compensation from the Company comprised substantially all of his publicly reported income for 2020.

32. Defendant James F. Young ("Young") has served as a director of Novavax since 2010 and as Chairman of the Board since 2011. He is the Chair of the R&D Committee. Young received $533,780 in total compensation from the Company for the fiscal year ended December 31, 2017; $471,715 in total compensation from the Company for the fiscal year ended December 31, 2018; $223,741 in total compensation from the Company for the fiscal year ended December 31, 2019; and $4,387,708 in total compensation from the Company for the fiscal year ended December 31, 2020. His compensation from the Company accounts for substantially all of his publicly reported income.

33. Defendant Gary C. Evans ("Evans") served as a director of Novavax from 1998 to June 2021.

34. Defendants Erck, Covino, Trizzino, Glenn, Herrmann, Alton, Douglas, McGlynn, Mott, King, McManus, Young, and Evans are sometimes referred to hereinafter as the "Individual Defendants."

IV. THE DUTIES OF THE INDIVIDUAL DEFENDANTS

A. Fiduciary Duties

35. By reason of their positions as officers, directors, and/or fiduciaries of Novavax and because of their ability to control the business and corporate affairs of Novavax, at all relevant times, the Individual Defendants owed Novavax and its stockholders fiduciary obligations of good faith, loyalty, and candor, and were required to use their utmost ability to control and manage Novavax in a fair, just, honest, and equitable manner. The Individual Defendants were required to act in furtherance of the best interests of Novavax and its stockholders so as to benefit all stockholders equally and not in furtherance of their own personal interest or benefit. Each director and officer of the Company owes to Novavax and its stockholders a fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

36. Because of their positions of control and authority as directors and/or officers of Novavax, the Individual Defendants were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Novavax, each of the Individual Defendants had knowledge of material non-public information regarding the Company.

37. To discharge their duties, the officers and directors of Novavax were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Novavax were required to, among other things:

(a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

(b) Exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority;

(c) Exercise good faith to ensure that the Company's communications with the public and with stockholders are made with due candor in a timely and complete fashion; and

(d) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

B. **The Board Committee Charters**

38. At all relevant times, the Board had four standing committees: (i) the Audit Committee; (ii) the Compensation Committee; (iii) the Nominating & Corporate Governance Committee, and (iv) the Research & Development Committee.

39. The Audit Committee is tasked to assist the Board with overseeing: (i) "the Company's accounting and financial reporting processes;" (ii) "the preparation, presentation and integrity of the financial reports and other financial information provided by the Company to any government or regulatory body, the public or other users thereof;" (iii) "the adequacy and efficacy of the Company's systems of internal accounting, auditing and financial controls, the Company's compliance with legal and regulatory requirements;" (iv) "the conduct, independence and qualifications of the Company's independent auditor;" (v) "the performance of the annual independent audit of the Company's financial statements;" (vi) "the Company's compliance with applicable federal and state laws and regulations;" and (vii) "the implementation and operation of

the Company's corporate compliance program."[2]The words "manufacturing," "safety," "CDMO" or "cGMPs" do not appear in the Audit Committee Charter. The word "quality" appears in the Audit Committee Charter only in the context of evaluating the Company's principal auditors and not in the context of the Company's products.

40. The Compensation Committee is tasked with assisting the Board "with its responsibilities relating to compensation of the Company's officers and directors and the development, administration, and oversight of the Company's compensation and benefits plans."[3] The words "manufacturing," "quality," "safety," "CDMO," or "cGMPs" do not appear in the Compensation Committee Charter.

41. The Nominating & Corporate Governance Committee is tasked with assisting the Board with its oversight responsibilities by: (i) "reviewing and making recommendations to the Board regarding the Board's size, structure and composition; establishing criteria for Board membership;" (ii) "identifying and evaluating candidates qualified to become members of the Board, including candidates proposed by stockholders;" (iii) "recommending to the Board for selection of director nominees to be presented for approval at the annual meeting of stockholders and to fill vacancies on the Board;" (iv) "considering the qualifications, tenure, and performance of incumbent members of the Board in determining whether to recommend that they be nominated for reelection;" (v) "evaluating Company policies relating to the recruitment of Board members; (vi) "developing and recommending to the Board corporate governance policies and practices applicable to the Company; (vii) "overseeing policies and practices with respect to

[2] *See* Novavax Fifth Amended and Restated Audit Committee Charter (the "Audit Committee Charter"), https://novavax.widen.net/s/l55pc2vqpx/audit_committee_charter_20210916.

[3] *See* Novavax Seventh Amended and Restated Compensation Committee Charter (the "Compensation Committee Charter"), https://novavax.widen.net/s/t6mhrp96wq/compensation_committee_charter_20211209

corporate social responsibility and environmental sustainability applicable to the Company;" and (viii) "overseeing management's plans for succession to senior management positions in the Company."[4] The words "manufacturing," "quality," "safety," "CDMO," or "cGMPs" do not appear in the Compensation Committee Charter.

42. The R&D Committee's "primary purpose" is to assist the Board "in reviewing and assessing the Company's research and development ('R&D') programs, and overseeing the Company's strategy and investment in R&D programs, and to perform such other functions as may be deemed necessary or appropriate in carrying out the foregoing."[5] The R&D Committee Charter charges the R&D Committee with the following specific responsibilities:[6]

> 1. ***Review and assess the Company's R&D programs, with the Committee Chair playing a day-to-day role providing input on key aspects of such R&D programs;***
>
> 2. Evaluate the Company's progress in achieving R&D goals and objectives, and make recommendations to the Board on modifications to the Company's R&D goals and objectives;
>
> 3. ***Advise the Board on the scientific and R&D aspects of licensing, strategic partnerships, and acquisition or divestiture transactions***;
>
> 4. Review and assess the Company's intellectual property portfolio and strategy;
>
> 5. ***Review the Company's regulatory efforts and strategy***;

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[4] *See* Novavax Fifth Amended and Restated Nominating and Corporate Governance Committee Charter (the "Nominating & Corporate Governance Committee Charter"), https://novavax.widen.net/s/kzkjssfttq/nominating_and_corporate_governance_committee_charter_20211209.

[5] *See* Novavax Research and Development Committee Charter (the "R&D Committee Charter"), https://novavax.widen.net/s/xhr5zwxgqm/research_and_development_committee_charter_20201214.

[6] *Id.* Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

> 6. ***Oversight of management's exercise of its responsibility to assess and manage risks associated with the Company's R&D programs and regulatory matters***;
>
> 7. Identify and report to the Board on significant emerging science and technology issues and trends that may impact the Company;
>
> 8. Serve as a resource for management to consult on any such topics regarding scientific and regulatory matters as reasonably requested; and
>
> 9. Select, retain, and supervise any advisors as the Committee deems necessary, in its discretion, to fulfill its mandates under this Charter, and compensate, at the expense of the Company, such advisors.

43. Nevertheless, the R&D Committee Charter does not contain the words "manufacturing," "quality," "safety," "CDMO," or "cGMPs" Accordingly, not one of the Company's four Board committees is directly charged with assisting the Board in overseeing the Company's manufacturing organization and operations; its compliance with cGMPs (*i.e.,* Current Good Manufacturing Practices); quality or safety assurance; or the use of CDMOs.

V. SUBSTANTIVE ALLEGATIONS

A. Background

44. Novavax is a late-stage biotechnology company that seeks to promote "improved global health through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases and address urgent, global health needs."[7]

45. In the past, the Company has attempted to develop vaccines for HIV, SARS, swine flu, and the Ebola virus, but each candidate either failed in testing or became obsolete as the epidemics ebbed.

46. Amid substantial doubt about the Company's ability to continue as a going concern, Novavax sold its manufacturing facilities for approximately $18 million in mid-2019 to stem its

[7] Novavax, Inc., Annual Report (Form 10-K) (Mar. 1, 2021) at 5.

financial losses. As a result of the transactions and related attrition, the Company reduced its headcount by more than 200 employees.

47. As of March 2020, Novavax had 127 employees engaged primarily in research, development and manufacturing activities. The Company was at risk of being delisted from the Nasdaq stock exchange as its stock traded under $4 per share and had just enough cash to survive another six months.

1. **Covid-19 Gives the Company a Lifeline**

48. In late 2019 and early 2020, a novel respiratory coronavirus – Covid-19 – sparked a once-a-century global pandemic.

49. Although the Company had never successfully brought a vaccine to market in its 35 year history, the Company announced its intention to develop a Covid-19 vaccine on February 26, 2020.

50. On March 10, 2020, Novavax received $4 million in funding from the Coalition for Epidemic Preparedness Innovations, a global partnership among organizations to accelerate the development of vaccines for emerging infectious diseases.

51. On April 8, 2020, Novavax announced that it would initiate a first-in-human trial in mid-May for its coronavirus vaccine candidate, NVX-CoV2373, a stable, prefusion protein created using the Company's proprietary technology.

52. The development and success of NVX-CoV2373 was critical for the Company. As one analyst noted, "the future financial success of [Novavax] and its ability to record a positive bottom-line result is highly dependent on successful approvals and rapid commercialization of its Covid-19 vaccine."

53. Unbeknownst to shareholders, as of early April 2020, the Novavax's executives were pressuring government officials to secure financing for their vaccine development. A

whistleblower action filed by Dr. Rick Bright, then-director of the U.S. Biomedical Advanced Research and Development Authority ("BARDA") until his removal in April 2020, alleges that on April 10, 2020, Erck called Dr. Bright's office requesting to speak directly with Dr. Bright about Novavax' proposal for a COVID-19 vaccine. The whistleblower complaint further alleges that on April 13, 2020, Novavax' Senior Vice President of Commercial Strategy, Brian Rosen ("Rosen"), circumvented Dr. Bright's office entirely and sent an email directly to Dr. Bright's supervisor, Dr. Kadlec, who was the Assistant Secretary for Preparedness and Response, touting the Company's vaccine in an effort to obtain funding.

54. On April 16, 2020, the Board convened a meeting where it received an update on NVX-CoV2373. In addition to members of the Board, defendants Glenn and Hermann, and Rosen, among other executives, were present. The discussion addressed the need for financing to initiate large scale manufacturing and focused on leasing a facility in the Czech Republic to scale up production. The meeting then addressed "funding activities" led by Rosen. As of this date the Company only had received $4 million from CEPI. As set forth above, it had already begun to violate myriad rules concerning contacting the government to exert pressure on a former executive and his superior to secure funds. Indeed, the minutes reflect that Rosen reported on ongoing discussions with CEPI, the Gates Foundation, the U.S. government, and a potential arrangement with Takeda Pharmaceutical Company Limited.

55. Accordingly, as of April 16, 2020, the Company was in ongoing discussions and lobbying multiple funding partners including BARDA, which had not been publicly disclosed.

56. At meetings on April 17 and April 18, 2020, the Compensation Committee of the Board approved equity-based awards to several executives, including Erck, Trezzino, Glenn, and Herrmann, worth over $60 million "in recognition of the extraordinary work of Novavax

employees to implement a new vaccine program against SARS-CoV-2 and to incentivize the additional work necessary to make the program successful…"

2. The US Government Gives the Company Over $1.6 Billion to Develop its Vaccine Candidate

57. On June 4, 2020, Novavax announced that it was awarded up to $60 million by the U.S. Department of Defense ("DoD") for the production of "several components" of its COVID-19 vaccine candidate, including "a 2020 delivery of 10 million doses of NVX-CoV2373 for DoD that could be used in Phase 2/3 clinical trials or under" emergency regulatory approval. To that end, Novavax would work with one or more CDMOs "to manufacture the antigen component of NVX-CoV2373 for at least 10 million doses of vaccine" and scale up production.

58. On July 7, 2020, Novavax announced that it was selected to participate in Operation Warp Speed ("OWS"), the U.S. government's $10 billion effort to develop and deliver a COVID-19 vaccine. Specifically, the Company was "awarded $1.6 billion by the federal government to complete late stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373… as early as late 2020." As a condition of the award, Novavax was required to demonstrate it could scale up manufacturing the vaccine candidate.

59. On this news, Novavax stock, which closed at $79.44 per share on July 6, 2020, rose over 30% in one day to close at $104.56 per share on July 7, 2020.

B. Novavax Expands its Manufacturing Capabilities and Anticipates Seeking Regulatory Approval of its COVID-19 Vaccine by Second Quarter 2021

60. Having sold its own manufacturing facilities in 2019 to alleviate its cash crunch, on July 23, 2020, Novavax announced that it had entered into an agreement with a CDMO, Fujifilm Diosynth Biotechnologies ("FDB"), to manufacture bulk drug substance for NVX-CoV2373. In fact, FDB's North Carolina site had already begun production of the first batch, which would be

"utilized in a future pivotal Phase 3 clinical trial of up to 30,000 subjects which is expected to begin in the fall of 2020 and which will determine the safety and efficacy of NVX-CoV2373." As Defendant Trizzino later acknowledged, the "antigen produced at the Fuji sites in North Carolina and Texas are a critical component of our US supply chain."[8]

61. On November 9, 2020, Novavax announced that the FDA had granted "Fast Track Designation for NVX-CoV2373." Such designation is the FDA's procedure to "facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need."

62. On February 4, 2021, Novavax announced that it had begun the rolling review for authorization of NVX-CoV2373 by multiple regulatory agencies, which was contingent on the pivotal Phase 3 trials. Later that month, the Company completed enrollment of PREVENT-19, its Phase 3 trial evaluating the safety, efficacy, and immunogenicity of NVX-CoV2373.

63. On March 1, 2021, Novavax filed with the SEC its annual report on Form 10-K for the year ended December 31, 2020 (the "2020 10-K"), which disclosed that the Company planned "to file submissions for Emergency Use Authorization ('EUA') with the FDA and expect[ed] to complete [its] EUA filing in the second quarter of 2021."[9] With respect to the manufacturing of NVX-CoV2373, the Company stated in the 2020 10-K that it had "secured fill/finish activities for NVX-CoV2373 at several sites globally."[10] The Company cited to "various manufacturing partnerships," announcing a "projected global manufacturing production rate of

[8] Testimony of John Trizzino at the Hearing on "Pathway to Protection: Expanding Availability of COVID-19 Vaccines" on February 23, 2021 before the House Subcommittee on Oversight and Investigations, *available at* https://docs.house.gov/meetings/IF/IF02/20210223/111226/HHRG-117-IF02-Wstate-TrizzinoJ-20210223.pdf

[9] Novavax 2020 10-K at 9.

[10] *Id.* at 55.

NVXCoV2373" of more than 2 billion doses annually once manufacturing was at full capacity, which Novavax expected "to occur in mid-2021."[11]

64. The same day, the Company issued a press release announcing its fourth quarter and full year 2020 results, which confirmed the statements made in the 2020 10-K. In addition to reiterating projected global manufacturing capacity of more than 2 billion annualized doses by mid-2021, the press release noted that the Company had "[e]ngaged in ongoing dialogue with [the FDA]…with potential for EUA filing in the second quarter of 2021."[12] The press release also quoted Erck, who stated that "Novavax continues to make significant strides towards bringing NVX-CoV2373, our Covid-19 vaccine candidate, to market."[13] Erck also touted various attributes of the vaccine that would purportedly "support emergency use authorization."[14]

C. The Company's Quality Controls Were Gravely Deficient

1. Novavax Was Required to Adhere to the FDA's Strict Manufacturing Regulations

65. Vaccine development and manufacture is a highly regulated industry. Novavax must adhere to FDA regulations governing the development and production of its vaccine candidates as well as CGMPs which "provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities" and "assure[] the identity, strength, quality,

[11] *Id.*

[12] Press Release, *Novavax Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights* (Mar. 1, 2021), https://ir.novavax.com/2021-03-01-Novavax-Reports-Fourth-Quarter-and-Full-Year-2020-Financial-Results-and-Operational-Highlights.

[13] *Id.*

[14] *Id.*

and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations." [15]

66. Moreover, regulations require Novavax to maintain records that "include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays."[16] This includes a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested."[17]

67. The Company must also adopt written procedures "designed to prevent objectionable microorganisms in drug products" and "designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products."[18] These procedures must include "provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications."[19]

68. These regulations apply even if Novavax's vaccine candidate would be developed at its partners' facilities. cGMP requires Novavax to establish a "quality control unit… responsible for approving or rejecting drug products manufactured, processed, packed, or held ***under contract by another company***."[20] The quality control unit is also "responsib[le] for approving or rejecting

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[15] *Facts About the Current Good Manufacturing Practices (CGMPs)*, FDA (June 1, 2021), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps.

[16] 21 C.F.R. § 211.194(a).

[17] 21 C.F.R. § 211.194(a)(6).

[18] 21 C.F.R. § 211.113; 21 C.F.R. §211.56(c).

[19] 21 C.F.R. § 211.198(a).

[20] 21 C.F.R. § 211.22(a).

all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."[21]

69. The 2020 10-K acknowledges that the Company's third party facilities must comply with these standards. Specifically, it states that "[t]o supply products for use either in the U.S. or outside the U.S., including clinical trials, U.S. and foreign manufacturing establishments, including third-party facilities, must comply with GMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in their home country." The 2020 10-K further notes that "vendors that supply [the Company's] key manufacturing materials have been or will be audited for compliance with GMP standards."

70. Novavax must also ensure that "responsible officials of the [Company], if they are not personally involved in or immediately aware of such actions" are notified in writing of any investigations, recalls, inspection reports, or regulatory actions relating to cGMP.[22] As such, the Company was required to comply with regulations governing its product manufacturing quality and safety and establish effective controls to monitor manufacturing safety and product integrity, including manufacturing at CDMOs (collectively, "Product Manufacturing Quality and Safety"). Failure to do so would expose the Company to significant risk that it would be unable to obtain FDA approval to market its vaccines.

71. Thus, it is mission critical that management and the Board exercise the highest degree of diligence and care to ensure the Company's implementation of effective internal controls and compliance with cGMPs and health and safety regulations mandated or enforced by the FDA and other regulators.

[21] 21 C.F.R. § 211.22(c).

[22] 21 C.F.R. § 180(f).

72. [redacted]

2. Unbeknownst to Stockholders, the FDA Had Cited Severe Manufacturing Deficiencies at Novavax's Facilities

73. Unbeknownst to the public and the Company's stockholders, the quality control at the facilities tasked with manufacturing the Company's vaccine fell short and imperiled the Company's ability to deliver on its already optimistic promises. According to documents produced in response to Plaintiffs' FOIA request, the FDA had issued several inspection reports during 2021 identifying these deficiencies.

74. Between March 15 and 19, 2021, the FDA inspected FDB's Texas facility to assess whether there were "controls in place to ensure that manufacturing operations are unlikely to

adversely impact the safety, purity, and potency of" the vaccines under development.[23] The FDA identified several "Items of Concern," including[24]:

- "Quality oversight over manufacturing and testing operations is sub-optimal. We identified several examples where deviations were not detected and documented appropriately and where change controls were not opened when appropriate."
- "Periodic review of deviation trending is not performed by the Quality Unit."
- "Written procedure for the OOS [i.e., out-of-specification] result investigation was not always followed. . . . In addition, without adequate justification the ***originally confirmed OOS results were later invalidated by the firm's investigation impact analysis***."
- Manufacturing areas were cleaned using disinfectants that "failed one or more microbial log reduction acceptance" tests and the "[c]leaning procedure for the classified manufacturing areas was not always followed"
- Warehouse areas used for storage of cGMP materials were "overcrowded and poorly organized"

75. Similarly, between April 14-21, 2021, the FDA investigated FDB's North Carolina facility and noted the following deviations in its inspection report:

> (a) Microbial control of the facility was inadequate. Specifically, the facility's employees failed to investigate root causes and implement adequate corrective and preventative actions to control microbial contamination, as exemplified by the FDA learning from prior reports that microbial contamination was recovered from over 50 monitoring sites, including purification sites.

[23] "EUA Investigation for FUJIFILM Diosynth Biotechnologies Texas, LLC (FDBT); Investigation Dates: 15-19 March 2021" (Apr. 14, 2021), at 1.

[24] *Id.* at 47-48.

(b) There was no comprehensive risk assessment conducted to evaluate cross-contamination of drug products, including where such drug products were manufactured in the same areas with shared product contact equipment.

(c) The manufacturing process was not adequately monitored and/or controlled to ensure the quality of the drug substance was not adversely affected.

(d) Written procedures for manufacturing processes were inadequate, including inadequate procedures for the "Purification" step.

(e) Discrepancies were not fully investigated to identify a root cause and corrective and preventative actions were not adequately implemented to prevent recurrence.

(f) Procedures of material management systems were not followed or were inadequate, which led to expired materials being found in the warehouse.

76. When FDB's Texas facility was investigated in August 2021, the FDA issued a Form 483 identifying many of the same deficiencies that had existed five months earlier, including[25]:

- "[N]ot adequate controls to prevent cross-contamination of other products in [the] multiproduct facility."
- Failure to adequately investigate batch contaminations
- Failure to comply with existing contamination control strategy
- Employees were not adequately trained for bulk substance manufacturing, and training records were missing
- "[N]o quantitative or specific measurements taken to qualify [redacted] equipment used in [redacted] bulk drug substance manufacturing"

[25] Form 483 issued to FUJIFILM DioSynth Biotechnologies Texas, LLC (Aug. 31, 2021), at 1-5.

- "Data integrity (D.I.) corrective measures are inadequate because [the facility has] not assessed all analytical instrumentation for possible correction"
- Lack of procedures/policies to appropriately test materials from outside sources

77. [redacted]

D. **The Individual Defendants Cause the Company to Issue Materially False and Misleading Statements**

78. Beginning February 2021, the Individual Defendants caused Novavax to issue materially misleading statements that the Company was "aligned" with the FDA's criteria, despite knowing of the widespread manufacturing deficiencies at its facilities.

79. On February 24, 2021, defendant Glenn provided an interview to *The Washington Post* regarding Novavax's progress, during which he stated: "We lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and so ***we're aligned up with those success criteria in all of our trials.***" As a result, the Company's stockholders anticipated Novavax would soon seek regulatory approval, with analysts at Jefferies stating that "[a]ltogether, everything remains on track, including EUA filing in UK, EU and USA in ***Q2***."

80. [redacted]

81. [redacted]

[redacted]

82. [redacted]

[redacted]

83. [redacted]

[redacted]

[redacted]

84. [redacted] On May 10, 2021, *The Washington Post* reported that Novavax's Emergency Use Authorization ("EUA") "filing was delayed by manufacturing regulatory issues, until June at the earliest, according to four people who had recently been briefed on the [C]ompany's plans."[26] According to people briefed on the trial status, the delay was "due in part to a regulatory manufacturing issue related to an assay," a test "used throughout the manufacturing process to check the contents and quality of vaccines."[27]

85. After the market closed on May 10, the Company held an earnings call in connection with its first quarter 2021 results during which it confirmed that Novavax was unlikely to seek an EUA until July 2021 at the earliest.

86. On the news of the delayed regulatory filing, the Company's stock price fell over 20% over two consecutive trading sessions to close at $138.18 per share on May 11, 2021, an over $2.4 billion market capitalization loss..

87. Even then, however, the Company did not come clean about its troubles. During the same May 10 call, Erck stated: "Our timetable for regulatory filings, we know that we're delayed from where we thought we'd be at this point. But now we're giving guidance that ***nearly all of the major challenges have been overcome*** and we can clearly see the light at the end of the

[26] Carolyn Y. Johnson, *Maker of latest experimental vaccine will not seek authorization until July at the earliest*, THE WASHINGTON POST (May 10, 2021), https://www.washingtonpost.com/health/2021/05/10/novavax-coronavirus-vaccine/.

[27] *Id.*

tunnel." Erck further stated that the filing timetable would "'depend[] on completing the final phases of qualification and validation of the assays that are needed' to show regulators that the manufacturing process is consistent every time[.]"[28]

88. When pressed for the reasons for the delayed regulatory filing, Erck stated that "part of it has to do with manufacturing at different sites and showing comparability between the processes and the actual end product between the different sites."[29] Though he acknowledged that "it probably took a little longer than we expected to get a potency assay that was worked across," Erck assured that "I'm happy to say we did. ***We've crossed that bridge.*** We're – we made a big breakthrough there and we're now racing towards validating everything and putting it into a package."

89. On the same call, Erck continued to assure stockholders that Novavax had "eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine." He went on to confirm that Novavax's manufacturing facilities adhered to FDA standards, stating that the Company has "got[ten] to the point where [it has] successfully manufactured [its] drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants."

90. On June 14, 2021, Novavax held a call to discuss a clinical update with stockholders, during which Erck stated "***[w]ith each analysis, our trials proved that we are on the right track***. And today, with safety and efficacy that are consistent across all studies, our PREVENT-19 results reaffirm our strong belief in" NVX-CoV2373.

[28] *Id.*

[29] *Id.*

91. [redacted]

92. [redacted]

93. [redacted]

94. On August 5, 2021, the Company filed is quarterly report on Form 10-Q with the SEC (the "2Q21 10-Q"), which reiterated that Novavax did not plan to file submissions for EUA related to NVXCoV2373 with the FDA until the fourth quarter of 2021.[30] The 2Q21 10-Q also stated, *inter alia*, that the Company had funding that was "expected to support our plans to file submissions for EUA and licensure with the FDA" but that the U.S. government had recently instructed Novavax "to prioritize alignment with the FDA on our analytic methods before conducting additional U.S. manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made."[31] Despite this, the 2Q21 10-Q still continued to tout the Company's manufacturing capabilities as they related to NVX-CoV2373, noting that Novavax expected the remainder of its manufacturing capacity to "be ready by the end of the fourth quarter of 2021, which we expect will support total global manufacturing capacity of approximately 150 million doses per month."[32] Nevertheless, the Company's stock price fell 19% to close at $189.89 per share on August 6, 2021, a $3.4 billion market capitalization drop.

95. But Defendants continued to mislead investors. In an interview with *Reuters* published on August 5, 2021, Erck claimed that Novavax "appear[ed] to have got past (certain) supply issues and [is] now being able to produce at scale."

96. Similarly, during an earnings call held on August 5, 2021, Erck downplayed the significance of obtaining "alignment with the [FDA] on the Company's analytic methods," stating "there's always a time lag with the FDA these days." He further claimed that Novavax "remain[ed]

[30] Novavax, Inc., Quarterly Report (Form 10-Q) (Aug. 5, 2021) at 23.

[31] *Id.*

[32] *Id.* at 24.

on track to achieve manufacturing capacity of 100 million doses per month by the end of the third quarter of ’21 and 150 million doses per month by the end of the fourth quarter of ’21.” When asked “how much risk is there associated with addressing some of those last remaining issues that are the gating steps to those filings,” Erck replied that “the risk reduction is dramatic” and that “I think that it’s a matter of now mechanics of getting all the data – final data assembled and submitted.” He reassured that this would be “weeks,” not “months, so I’m not worried about the future submissions.”

97. During the same call, another analyst asked whether the Company could achieve the previously announced timelines, to which Erck replied: “I do. This is a very big transformation – transition of the [C]ompany we filed. We’ve now filed with the regulatory agencies in 3 countries, and we’ve got a complete filing package for those. We are finishing the additional requirements in the various countries that I mentioned. We’ve listed dates that we plan on making with a lot of confidence.”

98. Behind the scenes, Erck’s confidence was belied by the Company’s ongoing difficulties. [redacted]

99. [redacted]

100. [redacted]

101. [redacted]

[redacted]

102. [redacted]

[redacted]

103. [redacted]

[redacted]

104. [redacted]

[redacted]

[redacted]

105. [redacted]

106. [redacted]

107. [redacted]

108. [redacted]

[redacted]

109. [redacted]

E. **The Truth Emerges**

110. On October 19, 2021, a *Politico* article revealed the true state of Novavax's manufacturing of NVX-CoV2373. Titled '*They rushed the process': Vaccine maker's woes hamper global inoculation campaign*, the article reported that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards," such that the timeline for approval was still a year away.[34]

[33] *See* Food and Drug Administration, *Guidance for Industry Process Validation: General Principles and Practices* at 10, https://www.fda.gov/media/71021/download (last visited May 20, 2022).

[34] Sarah Owermohle, Erin Banco and Adam Cancryn, *'They rushed the process': Vaccine maker's woes hamper global inoculation campaign*, Politico (Oct. 19, 2021), https://www.politico.com/news/2021/10/19/novavax-vaccine-rush-process-global-campaign-516298.

111. *Politico* reported that the Company's production problems include "test[ing] the purity of the vaccine [with methods that] have fallen short of regulators' standards" and "prov[ing] that it can produce a shot that is consistently up to snuff."[35] For example, though it is "generally understood that each vaccine batch should reach at least 90 percent [purity]," Novavax "has struggled to attain anywhere close to that" and has shown "purity levels hovering around 70 percent."[36]

112. The *Politico* article also noted that U.S. officials lacked confidence in Novavax because its "manufacturing problems are seen as ***far more difficult***" than the "sanitary and design concerns" affecting another COVID-19 manufacturer, Emergent BioSolutions, Inc.[37] In fact, when Novavax was awarded the OWS contract, U.S. officials had "repeatedly warned the [C]ompany that it risked running into problems in scaling up the manufacturing of the shot," and specifically "that Novavax would have difficulty ensuring that the vaccine consistently met the FDA's rigorous quality standards once the vaccine went into mass production – the exact problem that has now stymied the company for months."[38]

113. On this news, the Company's stock price fell 14% to close at $136.86 per share on October 20, 2021.

114. Finally, on June 7th, 2022, the FDA's committee of independent experts voted to recommend the FDA authorize the Company's NVX-CoV2373 vaccine for use in the United States. The approval was not a ringing endorsement, but an indifferent shrug indicating the Company's long-awaited candidate brought nothing really new to the table, still presented risks,

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

and may not even guard against Omicron. The Company is also late to the market because 78% of the U.S. population has already had at least one vaccine dose while 66.7% is already fully vaccinated.[39]

115. As discussed above, the Company was one of the earliest participants in OWS, receiving $1.8 billion in taxpayer dollars, after which it struggled for years to manufacture and then test a candidate. At the same time, the Company's executives received outsized compensation and sold Company stock at inflated prices.

116. Though the vaccine is reportedly now 90% effective at preventing COVID-19, the underlying trials were conducted from December 2020 through September of 2021 - months before the highly contagious Omicron variant and various sub lineages became dominant in United States. Importantly, FDA officials and the Company admit there is no daily data available on the effectiveness of the vaccine against Omicron.

117. Dr. Lucia Lee, an official with the FDA's division of vaccine research, aptly said during her presentation to the committee that the study was conducted "quite a while ago" and "the cases that accrued were not during the time that omicron was circulating."[40]

118. In the same critical vein, committee member Dr. Eric Rubin, an infectious disease expert at Harvard, said he was disappointed that the Company did not present data on its vaccine's effectiveness against Omicron. However, Dr. Rubin said the data the Company did submit meets the same standard used to authorize Pfizer and Moderna's vaccines in December 2020 (before Omicron).

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[39] *See* https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-pop-5yr (last visited June 8, 2022).

[40] *See* https://www.cnbc.com/2022/06/07/novavax-covid-vaccine-clears-key-step-on-path-to-fda-authorization-after-committee-endorses-the-shot.html (last visited June 8, 2022).

119. Committee member Dr. Arthur Reingold, an epidemiologist at UC Berkeley, said he was skeptical that large numbers of vaccine-hesitant people would get Novavax's shot, given the evidence that the Company's vaccine might be associated with a risk of heart inflammation at comparable levels to the Pfizer and Moderna shots. Reflecting the tepid to cold reception, Dr. Reingold said "I'm a little skeptical about how many vaccine-hesitant are just waiting for this vaccine and are going to be convinced this is better for them than the vaccines available[.] On a population level I'm hoping to be proven wrong, but count me as skeptical about that."[41]

120. Committee member Dr. Cody Meissner, a pediatrician at Tufts University, said that there is clearly a link between COVID vaccines and myocarditis, though there is not enough data to say whether one Company's shot carries a higher risk. Several committee members said that they supported adding a warning about myocarditis, as is done for the mRNA vaccines currently. For example, Dr. Bruce Gellin, chief of global public health strategy for the Rockefeller Foundation's Pandemic Prevention Institute said, "we need to understand the mechanism here, because this infection and the vaccines against it are going to be with us for the foreseeable future."[42] He abstained from the committee's vote, but afterward said he was a "conditional yes."

121. Thus, after receiving billions of dollars in government funding, the Company produced a vaccine that does not confront extant risks presented by Omicron, is no better than existing vaccines, and presents health risks.

122. Notably, the Company's stock price did not strongly react to the news of the advisory panel's recommendation, closing at $50.11 per share on June 8, 2022, the first full trading

[41] *See* https://thehill.com/policy/healthcare/3514939-fda-panel-gives-nod-to-novavax-covid-19-shot/ (last visited June 8, 2022).

[42] *See* https://groyourwealth.com/business/novavaxs-covid-19-vaccine-backed-by-fda-advisers/ (last visited June 8, 2022).

day after the news was announced. By June 9, 2022, Novavax stock was trading below $43 per share, its lowest price since May 2020, and exponentially lower than the prices at which the insiders unloaded their shares.

F. The Individual Defendants Cause the Company to Issue a Materially Misleading Proxy Statement

123. On May 3, 2021, defendants Erck, Alton, Douglas, McGlynn, Mott, King, McManus, and Young issued a definitive proxy statement soliciting stockholder votes in advance of the Company's annual meeting to be held June 17, 2021 (the "Proxy"). In the Proxy, these eight defendants solicited stockholder votes in favor of six management proposals, including ratification of certain April 2020 equity awards ("Proposal 4")and certain June 2020 equity awards ("Proposal 4").

124. The Proxy disclosed that the Board had determined that defendant Erck was not independent. The Proxy further noted that the Board delegates risk oversight to its key committees. In particular, the R&D Committee "Periodically reviews and assesses our research and development programs" and "Oversees strategies and investments specific to research and development programs." Notably, however, the Proxy failed to disclose that none of the Company's four Board committees was directly charged with assisting the Board in overseeing the Company's manufacturing organization and operations; its compliance with cGMPs; quality or safety assurance; or the use of CDMOs.

125. In connection with Proposal 4 and Proposal 5, the Proxy explained that in 2020, it had issued the following equity awards to Company executives "***in recognition of the extraordinary work of Novavax employees to implement a new vaccine program against SARS-CoV-2 and to incentivize the additional work necessary to make the program successful***…":

126. Moreover, the Proxy touted the Company's receipt of OWS funding as a major accomplishment of leadership. For example, in a section titled "2020 Performance Highlights," the Proxy stated:

> The Compensation Committee believes that the 2020 compensation of all our employees, including our Named Executive Officers, is appropriate not only due to the achievement of critical milestones under exceedingly difficult conditions, but also because it serves to continue to encourage their extraordinary efforts towards the achievement of our key priorities and anticipated milestones in 2021 and beyond. Over the past year, we leveraged our years of vaccine expertise to help global health authorities address, control and eradicate the SARS-CoV-2 virus.

April 2020 Options Awards

Recipient	**Number of Options**	**Value**
Stanley C. Erck	400,000	$31,664,800
John J. Trizzino	140,000	$11,082,680
Gregory M. Glenn, M.D.	165,000	$13,061,730
John A. Herrmann III	125,000	$9,895,250
Brian Rosen	115,000	$9,103,630
Total:	**945,000**	**$74,808,090**

June 2020 Options Awards

Recipient	**Number of Options**	**Value**
Richard H. Douglas, Ph.D.	6,900	$515,767
Gary C. Evans	6,900	$515,767
Rachel K. King	6,900	$515,767
Michael A. McManus, Jr.	6,900	$515,767
David M. Mott	4,400	$328,895

James Young, Ph.D.	15,180	$1,134,687
Total:	**47,180**	**$3,526,650**

June 2020 RSUs

Recipient	**Number of RSUs**	**Value**
John J. Trizzino	2,500	$208,850
John A. Herrmann III	2,500	$208,850
Total:	**5,000**	**$417,700**

127. The Proxy further explained that a shareholder of the Company had filed a derivative action challenging the propriety of these equity awards, worth collectively $78,752,440. In the Proxy, the Board solicited shareholder votes to ratify the awards to insulate the Board from liability in connection with their issuance and to moot the derivative action's challenge to their propriety.

128. The Proxy statement disclosed that the awards were issued to reward and incentivize defendants in connection with the Company's selection by the U.S. government to receive "Operation Warp Speed" funding:

> [A]s of June 25, 2020, Novavax was in discussions with the U.S. government program that was then called "Operation Warp Speed" regarding a Statement of Work for potential funding in the near-term… Novavax understood it had been selected as a candidate for Operation Warp Speed funding, and management was optimistic that the aggregate amount of such funding would exceed $1 billion… At a highly publicized meeting at the White House on March 2, 2020, for example, Mr. Erck told then-President Trump: "Frankly, we need money. We're a biotech company, and not one of the larger pharma companies, so we need money to get scale." On June 4, 2020, after Novavax announced a $60 million contract with the U.S. Department of Defense to support the manufacturing of NVX-CoV2373, an equity analyst from Cantor Fitzgerald published a report noting that Cantor Fitzgerald "anticipated additional funding from government organizations" for

> Novavax, "although [Novavax] was not part of the 'unofficial' list of 5 'finalists' for Operation Warp Speed." On June 8, 2020, also referencing Novavax's $60 million contract with the Department of Defense, an equity analyst from B. Riley FBR published a report noting that "this development further strengthens our conviction in a sizeable funding to be secured from U.S. BARDA."

129. In support of the Board's request that shareholders ratify the awards to moot the pending derivative claim challenging them, the Proxy stated:

> The Board of Directors… is seeking stockholder ratification of each of the April 2020 Awards and the June 2020 Awards because it does not believe further prosecution of the action is in the best interests of the Company, and seeks stockholder input regarding that determination. The individuals named as defendants dispute the allegations that the April 2020 Awards and the June 2020 Awards were spring-loaded, and they deny that they breached their fiduciary duties in granting or accepting them. The individuals named as defendants also dispute the allegations that the April 2020 Awards and the June 2020 Awards constituted corporate waste or unjustly enriched the recipients. The Board, not including the Recused Directors, believes that the litigation could take years to resolve, and that continued uncertainty associated with the litigation will reduce the incentive value of the April 2020 Awards and the June 2020 Awards.

130. The Proxy solicitation to ratify the April 2020 and June 2020 Awards was materially misleading because in seeking shareholder votes to ratify exceptionally large equity awards to insiders on the basis that the award "is appropriate not only due to the achievement of critical milestones under exceedingly difficult conditions, but also because it serves to continue to encourage their extraordinary efforts towards the achievement of our key priorities and anticipated milestones in 2021," it omitted to disclose that the Company was beset of manufacturing problems that likely precluded its vaccine from even coming to market and the Board lacked a system to oversee mission-critical compliance risks related to vaccine production, demonstrating that the very recipients of the to-be-ratified awards had not adequately discharged their fiduciary responsibility to ensure that the Company complied to critical FDA rules and regulations.

131. On June 24, 2021, Novavax filed a Form 8-K with the SEC disclosing that both Proposal 4 and Proposal 5 were adopted by the shareholders.

G. Defendants Sold Nearly $90 Million of Novavax Stock While in Possession of MNPI

132. As set forth above, defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young possessed adverse MNPI about the Company's business and prospects which they knew was not yet disclosed to the public. Defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young consciously acted to exploit their knowledge of this adverse MNPI by selling over $87.7 million in Novavax stock during the period between February 24, 2021 and October 19, 2021 (the "Sales Period").

133. Erck made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
7/1/2021	52,620	$212.88	$11,201,512.88
7/2/2021	52,559	$215.89	$11,347,066.13
10/1/2021	49,000	$175.10	$8,580,063.84
10/4/2021	42,829	$176.15	$7,544,194.71
		TOTAL PROCEEDS:	**$38,672,837.56**

134. Defendant Erck's sales are particularly suspicious as they represented nearly 88% of his stock holdings. Further, Erck sold four times more of his personally held stock during the Sales Period than he did during the same amount of time immediately preceding the sales period (July 1, 2020 to February 23, 2021), selling approximately $38.7 million compared to $9.4 million. Since the end of the Sales Period, defendant Erck has not sold any of his personally held Novavax stock.[43]

[43] Plaintiffs do not include in their analysis Code F transactions, which are those transactions that consist of "payment of exercise price or tax liability using portion of securities received from the company" or Code D transactions, which are forfeits of stock back to the Company. https://www.sec.gov/files/forms-3-4-5.pdf

135. Evans made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
3/15/2021	24,500	$211.21	$5,174,645.00
6/1/2021	625	$146.50	$91,562.50
		TOTAL PROCEEDS:	**$5,266,207.50**

136. Evans sales are particularly as he sold over 56% of his Novavax stock. Further, during the Sales Period, Evans sold 3.5 times more stock than during the period immediately preceding the Sales Period, when he sold $1.6 million worth of Novavax sock. Evans has not sold any stock since the end of the Sales Period.

137. Glenn made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
3/15/2021	5,712	$198.60	$1,134,400.01
3/17/2021	2,423	$218.86	$530,304.32
4/15/2021	5,712	$201.35	$1,144,387.39
4/19/2021	2,417	$219.72	$531,051.77
5/17/2021	5,712	$133.98	$765,266.69
5/19/2021	2,385	$142.17	$339,066.44
6/15/2021	5,716	$191.42	$1,094,129.89
6/17/2021	2,411	$183.28	$441,886.87
7/15/2021	5,654	$179.45	$1,014,596.90
7/20/2021	2,409	$215.43	$518,981.91
8/16/2021	1,866	$233.52	$435,750.33
8/26/2021	4,167	$233.92	$974,740.02
8/31/2021	1,386	$239.87	$332,462.51
9/15/2021	1,183	$229.34	$271,304.34
9/27/2021	2,083	$234.43	$488,315.17
9/30/2021	693	$207.25	$143,621.67
10/5/2021	8,250	$174.41	$1,438,895.37
10/12/2021	8,250	$163.18	$1,346,217.97
10/15/2021	1,183	$170.00	$201,110.00
10/19/2021	8,250	$166.14	$1,362,427.31
		TOTAL PROCEEDS:	**$14,508,916.89**

138. Glenn's sales are particularly suspicious as he sold 82% of his Novavax holdings.

139. Herrmann made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
2/26/21	2,895	$225.48	$652,759.28
3/26/2021	2,894	$186.80	$540,599.20
4/30/2021	2,895	$239.83	$694,307.85
5/28/2021	2,895	$149.14	$431,760.30
6/30/2021	2,896	$212.65	$615,834.40
7/26/2021	2,896	$197.74	$572,655.04
9/1/2021	5,000	$247.97	$1,239,867.44
9/15/2021	5,000	$229.44	$1,147,193.48
10/1/2021	5,000	$174.89	$874,450.00
		TOTAL PROCEEDS:	**$6,769,442.44**

140. Hermann's sales are particularly suspicious as he sold almost 81% of his Novavax holdings.

141. Mott made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
9/23/2021	24,961	$252.90	$6,312,636.90
		TOTAL PROCEEDS:	**$6,312,636.90**

142. Mott's sales were particularly suspicious as he sold over 38% of his Novavax holdings. In addition, Mott has not sold stock before or after the Sales Period.

143. Trizzino made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
3/5/2021	3,021	$163.46	$493,824.02
3/9/2021	190	$168.09	$31,937.10
4/5/2021	3,021	$190.10	$574,292.10
4/7/2021	191	$178.03	$34,003.73
5/5/2021	3,022	$185.46	$560,470.61
5/7/2021	190	$176.63	$33,559.00
9/13/2021	7,499	$235.29	$1,764,433.22
9/14/2021	7,499	$236.61	$1,774,360.39

9/20/2021	7,500	$227.57	$1,706,673.69
9/21/2021	7,500	$227.37	$1,705,264.59
9/27/2021	7,501	$234.61	$1,759,832.92
9/28/2021	7,501	$209.92	$1,574,637.13
		TOTAL PROCEEDS:	**$12,013,362.98**

144. Trizzino's sales were particularly suspicious as he sold over 91% of his Novavax holdings. In addition, Trizzino has not sold at Novavax stock since the Sales Period.

145. Young made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
3/23/2021	10,000	$228.42	$2,282,230.78
		TOTAL PROCEEDS:	**$2,282,230.78**

146. McManus made the following sales of stock before the MNPI was fully disclosed to the public:

Date	Shares Sold	Avg. Price Per Share	Proceeds
3/19/2021	4,000	$220.78	$883,100.00
		TOTAL PROCEEDS:	**$883,100.00**

VI. DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

147. Plaintiffs repeat and reallege each and every allegation set forth above, as though fully set forth herein.

148. Plaintiffs bring this action derivatively, and in the right and for the benefit of Novavax to redress the Individual Defendants' misconduct.

149. Plaintiff are stockholders of Novavax, were stockholders of Novavax at the time of the wrongdoing alleged herein, and have been stockholders of Novavax continuously since that time.

150. Plaintiffs will adequately and fairly represent the interests of Novavax in enforcing and prosecuting its rights.

151. As a result of the facts set forth herein, Plaintiffs have not made any demand on the Board to institute this action. Such a demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and prosecute this action.

152. Novavax's Board of Directors consists of eight directors: defendants (i) Erck, (ii) McManus, (iii) Mott, (iv) Young, (v) Alton, (vi) Douglas, (vii) King, and (viii) McGlynn.

The Entire Board Faces a Substantial Risk of Liability for Count I

153. Demand is excused as to Count I (violations of Section 14 of the Exchange Act) because the entire Board faces a substantial likelihood of liability for this claim.

154. Specifically, the entire current Board, Erck, McManus, Mott, Young, Alton, Douglas, King, and McGlynn knew or recklessly failed to inform themselves that: (i) the FDA had identified manufacturing deficiencies at facilities used to manufacture the Company's Covid-19 vaccine; and (ii) the Board had failed to implement sufficient controls to oversee the Company's compliance with cGMPs at its contract manufacturing facilities.

155. Nonetheless, Erck, McManus, Mott, Young, Alton, Douglas, King, and McGlynn solicited shareholder votes to ratify over $70 million in challenged equity compensation to insiders that was issued to reward them for their success in overseeing the Company's efforts to develop a Covid-19 vaccine and incentivize continued best efforts in connection with the same, while concealing that those very same insiders had in fact presided over the manufacturing and internal control deficiencies detailed herein.

156. Due to Erck, McManus, Mott, Young, Alton, Douglas, King, and McGlynn's misleading proxy solicitation, the Company was harmed in an amount in excess of $70 million.

A Majority of the Board Faces a Substantial Risk of Liability for Count II

157. Demand is excused as to Count II (breach of fiduciary duty under *Caremark*) because the entire Board faces a substantial likelihood of liability for this claim because the entire Board failed to implement sufficient controls in good faith to oversee Novavax's compliance with cGMPs at its contract manufacturing facilities.

158. In particular, though manufacturing safe, quality controlled vaccines is "mission critical" to Novavax's operations, the Board still lacks a committee specifically tasked to oversee the Company's compliance with cGMPs. As set forth above, none of the Company's four standing committees was specifically charged with overseeing the Company's manufacturing controls and procedures.

159. Additionally, the Board failed to oversee the effectiveness of Novavax's manufacturing controls and procedures on a regular basis. Though no committee was specifically charged with the oversight of manufacturing controls and procedures, the entire Board also failed to exercise its oversight duties in this respect. Indeed, Board documents produced in response to the 220 Demands show that, though the Board met at least TK times between TK and TK, the Board did not review or discuss the Company's manufacturing activities or the results of the FDA's investigations into the Company's CDMO facilities, the contents of the FDA's reports concerning the foregoing, or what if any remedial measures should be taken.

160. More specifically, the Board documents produced in response to Plaintiffs' 220 Demands show:

a. There was no Board committee that specifically addressed manufacturing, CDMOs, or Product Manufacturing Quality and Safety.

b. There were no formal processes or controls that required management to keep the Board informed of manufacturing safety practices, risks, or reports;

c. There was no schedule for the Board to consider on a regular basis the existence of any manufacturing safety risk;

d. There was no indication that the audit reports identifying deficiencies were reviewed or disclosed to the Board; and

e. There was no discussion whatsoever by the Board of the Company's Product Manufacturing Quality and Safety.

161. As a result of the foregoing, the entire Board faces a substantial risk of liability, and demand is excused.

At Least Half the Board Received a Material Personal Benefit from Insider Trading

162. Demand is excused as to Count III (breach of fiduciary duty under *Brophy*) and Count IV (unjust enrichment) because at least half of the Board received a material personal benefit from this alleged misconduct. Specifically:

a. Erck reaped over $39 million from insider sales. This mid-eight-figure windfall is material for anyone. It was over *four times* his total compensation from the Company for 2017, 2018 and 2019 combined, and over 80% of his total compensation from the Company for 2020. Moreover, the Board concedes that Erck lacks independence.

b. Mott reaped over $6.3 million from insider sales, which is material to him because it was *over eight times* his 2020 compensation from the Company and over double his 2020 compensation from all publicly reported sources.

c. Young reaped over $2.2 million from insider sales, which is material to him because it was *over four times* his 2020 income.

d. McManus reaped $883,000, which is material to him because it is more than his entire 2020 compensation from the Company in 2020, as well as more than his total compensation from the Company and all other publicly reported sources in 2017, 2018 and 2019 combined.

163. As such, four out of the eight members of the Board received a material personal benefit from the insider sales which are alleged in Count III and Count IV below.

VII. CAUSES OF ACTION

COUNT I

Against Defendants Erck, Alton, Douglas, McGlynn, Mott, King, McManus, and Young for Violations of Section 14 of the Exchange Act

164. Plaintiffs repeat and reallege each and every allegation set forth above, as though fully set forth herein

165. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9. Specifically, the Company's Proxy filed on May 3, 2021 violated § 14(a) and Rule 14a-9 because it sought shareholder ratification of previously issued equity awards while omitted to disclose material information regarding whether the awards were warranted.

166. In the exercise of reasonable care, defendants should have known that the statements contained in the proxy statement were materially false and misleading.

167. The misrepresentations and omissions in the Proxy were material to Company stockholders in voting on the proxy statement. The Proxy solicited and obtained stockholder votes for ratification of the April 2020 and June 2020 Awards, which enriched insiders by nearly $80 million. The Proxy was an essential link in defendants insulation of the awards from shareholder challenge.

168. The Company was damaged as a result of the defendants' material misrepresentations and omissions in the Proxy.

169. No adequate remedy at law exists for Plaintiffs by and on behalf of the Company.

COUNT II

Against Defendants Erck, McManus, Mott, Young, Alton, Douglas, King and McGlynn for Breach of Fiduciary Duty (*Caremark*)

170. Plaintiffs repeat and reallege each and every allegation set forth above, as though fully set forth herein

171. As members of the Board, defendants Erck, McManus, Mott, Young, Alton, Douglas, King and McGlynn each owes and owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Novavax's business and affairs.

172. Defendants Erck, McManus, Mott, Young, Alton, Douglas, King and McGlynn failed to implement any Board-level oversight over Novavax's Product Manufacturing Quality and Safety to ensure the Company's compliance with applicable regulations and cGMPs, which is not a good faith exercise of business judgment. Accordingly, these defendants breached their duty of loyalty to the Company through their intentional, reckless or grossly negligent misconduct.

173. As a direct and proximate result of these defendants' breaches of their fiduciary obligations, Novavax has sustained and continues to sustain significant damages, including direct

monetary damages, exposure to liability from securities litigation and a loss of goodwill in the capital markets. As a result of the misconduct alleged herein, defendants are liable to the Company.

COUNT III

Against Defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young for Breach of Fiduciary Duty (*Caremark*)

174. Plaintiffs repeat and reallege each and every allegation set forth above, as though fully set forth herein.

175. As alleged above, defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young are fiduciaries of Novavax, possessed material non-public information of Novavax, and used that information improperly to profit from sales of Novavax stock. When Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young directed the stock sales set forth above, they were motivated to do so, in whole or in part, by the substance of the material non-public information they possessed, and they acted with scienter.

176. When defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young sold their Novavax stock, they knew that the investing public was unaware of the negative material information that they possessed. They also knew that if the information were disclosed, the market price of Novavax stock would be significantly lower. Defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young timed their stock sales to take advantage of the public's ignorance of the concealed facts and obtain a higher price for the stock they sold. They thereby benefited by misappropriating Novavax's non-public information.

177. Plaintiffs have no adequate remedy at law.

COUNT IV

Against Defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young for Unjust Enrichment

178. Plaintiffs repeat and reallege each and every allegation set forth above, as though fully set forth herein.

179. Defendants Erck, Evans, Glenn, Herrmann, McManus, Mott, Trizzino, and Young were unjustly enriched by their wrongful acts at the expense of and to the detriment of Novavax as a result of selling their Novavax stock at inflated prices on the basis and prior to the public release of adverse MNPI.

180. Under the circumstances, it would be against the principles of equity and good conscience to allow these defendants to retain these benefits.

181. Plaintiffs, on behalf of Novavax, have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of Novavax, demand judgment as follows:

A. Against all of the defendants and in favor of the Company for the amount of damages sustained by Novavax as the result of Defendants' misconduct alleged herein;

B. Awarding Novavax the amount of damages it sustained as a result of defendants' violation of Section 14 of the Exchange Act, breaches of fiduciary duty, and unjust enrichment;

C. Awarding to plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

D. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury.

Dated: June 10, 2022

By: */s/ Andrew Radding*

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Counsel for Plaintiffs

VERIFICATION

I, Charles R. Blackburn, do hereby verify that I am a holder of common stock of Novavax Inc. and was a holder of such common stock at the time of the wrongs complained of in the foregoing Verified Shareholder Derivative Complaint (the "Complaint"). I have reviewed and authorized the filing of the Complaint. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct.

June 7, 2022

Charles R. Blackburn

VERIFICATION

I, Michele Rosati, do hereby verify that I am a holder of common stock of Novavax Inc. and was a holder of such common stock at the time of the wrongs complained of in the foregoing Verified Shareholder Derivative Complaint (the "Complaint"). I have reviewed and authorized the filing of the Complaint. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct.

June 6/7/2022, 2022

DocuSigned by:
Michele Rosati
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Michele Rosati